

Claim Listing

This listing of claims will replace all prior versions, and listings, of claims in the present application.

1. (currently amended) A sustained-release pharmaceutical composition comprising granulocyte-colony stimulating factor (G-CSF) ~~incorporated into a biocompatible a polyol:oil suspension, wherein said suspension contains~~ and a thickener, and where said composition is prepared by a process which comprises:

(a) mixing a solution of G-CSF in a polyol to form a G-CSF:polyol composition mixture;

(b) suspending said G-CSF:polyol composition mixture in a composition mixture comprising a thickened oil to form a ~~G-CSF:polyol:oil suspension~~ wherein the level of said polyol in ~~said suspension~~ is in the range from 15%-30% by weight.

2. (currently amended) The pharmaceutical composition of Claim 1 wherein said biocompatible polyol is selected from the group consisting of glycerol, erythritol, arabinose, xylose, ribose, inositol, fructose, galactose, maltose, glucose, mannose, and sucrose.

3. (currently amended) The pharmaceutical composition of Claim 1 wherein said oil is selected from the group consisting of sesame, castor, cottonseed, canola, saffron, olive, peanut, sunflower seed, a-tocopherol, Miglyol 812, and ethyl oleate.

4. (currently amended) The pharmaceutical composition of Claim 13 wherein the thickener is aluminum monostearate.

5. (currently amended) The pharmaceutical composition of Claim 13 wherein the thickener is white wax.

6-7. (canceled)

8. (currently amended) A process for preparing sustained-release pharmaceutical compositions of G-CSF:polyol:oil suspensions which comprises:

(a) mixing a solution of G-CSF in a polyol to form a G-CSF:polyol composition mixture;

(b) suspending said G-CSF:polyol composition mixture in a composition mixture comprising a thickened oil to form a G-CSF:polyol:oil suspension wherein the level of said polyol in said suspension is in the range from 15%-30% by weight.

9-12. (canceled)

13. (currently amended) The pharmaceutical composition of Claim 1 wherein the thickener is selected from the group consisting of fatty acids, polyvalent metal salts of organic acids, alcohols, waxes and high-viscosity high viscosity oils.

14. (new) The pharmaceutical composition of Claim 1 further comprising a stabilizer selected from the group consisting of a surfactant and an emulsifier.

15. (new) The pharmaceutical composition of Claim 1 wherein the solution of G-CSF comprises a solvent selected from the group consisting of water and glycerol.

16. (new) The process of Claim 8 wherein the solution of G-CSF comprises a solvent selected from the group consisting of water and glycerol.

17. (new) The pharmaceutical composition of Claim 1 wherein said thickened oil comprises hydrogenated vegetable oil.